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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,884	01/21/2000	Terry R. Colbert	P04348US0-PHI-1194	6401

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PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/489,884

Applicant(s)

COLBERT, TERRY R.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-8, 20, 21, 33, 34, 41 and 42 is/are allowed.
- 6) ☒ Claim(s) 9-19, 22-32 and 35-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. This Office Action is in response to the Amendment and Remarks filed 11 December 2002.
2. New claims 33-42 have been added.
3. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. Claims 9-11, 13-19, 22-24 and 26-32 remain rejected and claim 39 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 September 2002. Applicant's arguments filed 11 December 2002 have been fully considered but they are not persuasive.

Claims 9, 13, 17, 22, 26 and 30 remain indefinite because said claims are directed to a method for developing a maize plant, yet said claims only recite the step of obtaining a maize plant or its part as a source of breeding material. There are no other positive method steps leading to the development of a maize plant in the claims. See MPEP § 2172.01. Applicant argues that the claims clearly define a method utilizing the proprietary hybrid 33T17 to produce maize plants and that the application clearly defines and distinctly claim positive method steps (paragraph spanning pages 9-10 of

the Remarks). This argument is not found to be persuasive because at the instant claims only state "obtaining the maize plant", yet one of skill in the art would clearly recognize that merely "obtaining the maize plant" does not state the metes and bounds of a method of developing a maize plant. Consequently, claims 10, 14, 18, 21, 27 and 31 remain rejected as indefinite because said claims do not obviate the indefiniteness of the claim upon which they depend.

At claims 11, 15, 19, 24, 28 and 32, the terms "yield ability", "food grade quality" and "test weight" for example, are relative and do not state the metes and bounds of the claimed invention. Even given the comparative statistical limitation in the instant claims, said terms do not denote properties specific to hybrid maize line '33T17' and thus do not state the metes and bounds of the claimed invention. Applicant argues that the recitation of 33T17 traits clearly delineates the traits listed as those, which are from 33T17 or ancestors thereof. Applicant argues that the adjectives used within the claims clearly characterize and positively recite the degree of expression of the particular traits within the application in Tables 1-4 (page 10, 3rd paragraph, and page 11, 1st paragraph of the Remarks). This argument is not found to be persuasive because the claimed traits are relative, many traits of which are controlled by multiple alleles within 33T17.

Claims 16 and 29 remain indefinite because it is unclear how one skilled in the art could produce the maize plant of claim 2 or 20 containing one or more genes transferred by backcrossing. The claimed hybrid maize plant is evidently not the hybrid maize plant of claim 2 or 20, but a new and different product. In addition, the instant claims are directed to a product-by-process but there are not process steps recited by

which one of skill in the art would or could produce the claimed product. Applicant argues the specification supplies an extensive definition and description of 'transgene' and transgenes of interest, and that a person of skill in the art could insert a DNA gene into a selected maize plant (page 11, 3rd paragraph of the Remarks). Applicant argues that said claims have amended said claims to read "further comprises" instead of "contains" (page 12, 1st paragraph of the Remarks). These arguments are not found to be persuasive because the maize plant of claim 2 or 20 is a hybrid, produced by two, unique inbred parent plants. Therefore, it remains unclear how one of skill in the art would arrive at the maize plant at claim 16 or 29 by backcrossing. If the maize plant at claim 16 or 29 further comprises one or more genes transferred by backcrossing, then said maize plant is very different from the maize plant at claim 2 or 20, respectively. Because there is no intermediate process for producing the maize plant at claim 16 or 29 from the maize plant of claim 2 or 20, respectively, then the metes and bounds of claims 16 and 29 remain unclear. There is no recitation of introducing a transgene in the instant claims as Applicant apparently argues in the response.

At claim 39, the claim is directed to a 33T17 maize plant said plant being produced by a method wherein the exemplified 33T17 maize plant is crossed with a second plant. Clearly the plant at claim 39 cannot be the maize plant of claim 2 designated 33T17 or produced by the method of claim 37, to which the instant claim is directed and only have 50% of it's alleles from the 33T17 maize plant of claim 2. Hence, it is unclear what the metes and bounds of the claimed invention are.

6. Claims 9-19 and 22-32 remain rejected and claims 35-40 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 September 2002. Applicant's arguments filed 11 December 2002 have been fully considered but they are not persuasive.

Applicant argues that deposit of variety '33T17' and the parental varieties GE515488 and GE534625 satisfies the written description requirement for the instant claims (page 13, 2nd paragraph of the Remarks). This argument is not found to be persuasive because the stated deposits only satisfy the written description requirement for the hybrid variety 33T17, not progeny thereof or derived plants.

Applicant argues that at claims 11, 15, 19, 24, 28 and 32, Applicant has added the threshold, having 50% of the alleles, as well as an assayable function, capable of expressing at least a combination of two traits of '33T17'. Applicant argues that under the written description requirement, Applicant should be allowed to claim the progeny of a cross of maize plants crossed with '33T17' with phenotypic characteristics and that in plants, identifying characteristics are those detectable in the phenotype which are manifested through gene expression. In addition, Applicant argues that one of ordinary skill in the art is reasonable apprised in knowing that a plant crossed with 33T17 will result in a plant having half of the genetic contribution of '33T17' (page 14 of the Remarks). This argument is not found to be persuasive because one of skill in the art

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would recognize that the '33T17' traits to which the claims refer are controlled by multiple genes at multiple loci and are not unique to hybrid '33T17'. Applicant does not describe the loci that contribute to the claimed traits, or how one of skill in the art would recognize that the 50% of the alleles from 33T17 have contributed to the two 33T17 traits.

Applicant argues that the present application clearly describes and defines a transgene to be a gene transferred into a plant wherein the product of that gene is expressed and that the trivial modifications introduced by the transgenes to the unique invention of '33T17' are clearly supported and described in the present application (page 15, 1st paragraph of the Remarks). This argument is not found to be fully persuasive because claims 12-15, 16-19 and 25-28 are directed to a transformed hybrid maize plant designated 33T17 or a hybrid maize plant comprising one or more genes transferred by backcrossing, and methods of using same, said transformed or backcrossed hybrid maize plant comprising any transgene or gene(s). Given the breadth of the invention in the instant claims it is unclear if Applicant was in possession of such a broad genus of transgenic or backcrossed hybrid maize plants at the time of the invention because Applicant does not clearly describe what effect all transgenes or genes introduced by backcrossing would have on the hybrid maize plant designated 33T17.

At new claims 35-40 Applicant has failed to adequately describe the products to which the instant claims are directed. Claim 36 reads on a maize plant produced by an unspecified number of self or sib pollinated crosses at claim 35. Because hybrid maize

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plant 33T17 is a cross between two inbred parental lines, each parent contributing essentially one gene at each locus to the genetic structure of the hybrid maize plant 33T17, one of skill in the art would recognize that in a self or sib cross, that each locus has the potential to rearrange and produce a new and unique genome. Given the number of loci that contribute to just the trait of yield, one of skill in the art could not envision the product at claim 36 produced by the method of claim 35. The art teaches that the probability of producing a favorable genotype for just one trait in maize can be on the order of 10^{-5} or lower, depending upon how many alleles control the desired trait (see Segebart 1994, U.S. Patent 5,367,109, columns 2-4). Likewise the population of 33T17 progeny maize plants or 33T17 maize plant at claims 38 and 39 produced by the method of claim 37, respectively, cannot be adequately described by only describing the hybrid maize plant 33T17. Claim 40 lacks adequate written description because it is dependent upon claim 37 and does not obviate the instant rejection as directed to claim 37.

The following amendments would obviate the rejection under 35 USC § 112, first paragraph:

Cancel claims 9-19, 22-32, 35-38, 39 and 40.

Submit new claims 43-51 below (support for said claims can be found in the specification, pages 27-38).

-- New claim 43. A method of producing an herbicide resistant maize plant comprising transforming the maize plant of claim 2 with a transgene that confers herbicide resistance.

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New claim 44. An herbicide resistant maize plant produced by the method of claim 43.

New claim 45. A method of producing an insect resistant maize plant comprising transforming the maize plant of claim 2 with a transgene that confers insect resistance.

New claim 46. An insect resistant maize plant produced by the method of claim 45.

New claim 47. A method of producing a disease resistant maize plant comprising transforming the maize plant of claim 2 with a transgene that confers disease resistance.

New claim 48. A disease resistant maize plant produced by the method of claim 47.

New claim 49. A method of producing a maize plant with decreased phytate content comprising transforming the maize plant of claim 2 with a transgene encoding phytase.

New claim 50. A maize plant with decreased phytate content, produced by the method of claim 49.

New claim 51. A method of producing a maize plant with modified fatty acid or carbohydrate metabolism comprising transforming the maize plant of claim 2 with one or more transgenes encoding a protein selected from the group consisting of stearyl-ACP desaturase, fructosyltransferase, levansucrase, alpha-amylase, invertase, and starch branching enzyme.

New claim 52. A maize plant produced by the method of claim 51. --

Claim Rejections - 35 USC § 102/103

7. Claims 11, 15, 19, 24, 28 and 32 remain rejected and claims 39 and 40 are rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Cunnyingham (US Patent 6,087,564, filed 13 February 1998). This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 September 2002. Applicant's arguments filed 11 December 2002 have been fully considered but they are not persuasive.

The issue of the lack of adequate written description as directed to the instant claims is discussed supra.

Applicant argues that the claimed plant cannot be rendered obvious as it possesses a unique combination of traits, which confers a unique combination of genetics (page 16, 2nd paragraph of the Remarks). The Examiner maintains the instant rejection as it is directed to subsequent progeny plants of the hybrid maize plant designated 33T17. Because Applicant is only able to describe the exemplified 33T17 hybrid maize plant based to a limited number of phenotypic traits, the instant claims directed to subsequent progeny plants, even those that have derived at least 50% of their ancestral alleles from 33T17, would have been indistinguishable from that of Cunnyingham. The Examiner notes that even though the claimed plant has 50% of its ancestral alleles from 33T17, the additionally claimed two 33T17 traits are controlled by multiple alleles, many of which would have been common to the 34P93 hybrid maize plant of Cunnyingham.

Applicant argues that the claims do not simply recite traits, but instead recites those specific traits only to the extent that they are "33T17" traits, thereby being derived from the seed/germplasm of 33T17. Applicant also argues that the claims also recites that the claimed plant must have 33T17 as an ancestor further indicating that these traits must originate from the 33T17 plant and not 34P93 (page 17, 4th paragraph of the Remarks). This argument is not found to be persuasive because the 34P93 hybrid maize plant taught by Cunnyingham is capable of transferring at least two of the same traits as Applicant's 33T17 plant. In addition, because Applicant only describes the 33T17 hybrid maize plant based on phenotypic characteristics, these are the only characteristics one of ordinary skill in the art at the time of Applicant's invention could use to compare progeny of Applicant's 33T17 hybrid maize plant with a progeny of Cunnyingham's 34P93 hybrid maize plant.

Applicant argues that there is no expectation of success that the crossing of the hybrid 34P93 with some yet to be identified plant would yield a plant with two traits enumerated in the claimed invention and at least 50% of its ancestral alleles from 33T17 because that particular plant did not begin with the claimed seed 33T17 which is essential (paragraph spanning pages 17-18 of the Remarks). This argument is not found to be persuasive because of the reasons given in the previous paragraph. In addition, Applicant does not teach 50% of the alleles of the exemplified 33T17 hybrid maize plant by which one of ordinary skill in the art could distinguish progeny of Applicant's 33T17 hybrid maize plant with a progeny of Cunnyingham's 34P93 hybrid maize plant.

Applicant argues that similarities in phenotype between two varieties is not the same as saying that the two varieties have the same morphological and physiological characteristics as a whole, or that one is an obvious variant of the other. Applicant also argues that similarity in phenotype does not mean that the two varieties will perform similarly, particularly in a breeding program (pagee 19, 1st paragraph of the Remarks). The Examiner responds that the Examiner does not consider the exemplified 33T17 hybrid maize plant of the instant invention to be anticipated or obvious in view of Cunnyingham's 34P93 hybrid maize plant. The Examiner has rejected progeny plants of Applicant's 33T17 hybrid maize plant as being indistinguishable from progeny plants of Cunnyingham's 34P93 hybrid maize plant based on phenotypic distinctions.

Applicant argues that Hybrid 34P93 does not exhibit the same characteristic as 33T17 (page 19, 2nd paragraph of the Remarks). This argument is not found to be persuasive, because the instant claims are directed to a maize plant expressing "at least two 33T17 traits", while the 34P93 hybrid maize plant inherently discloses such relative traits as "yield ability", "Gray Leaf Spot tolerance" and "tolerance to Fusarium Ear Rot" and thus such traits are not unique identifying traits for hybrid maize 33T17. In addition, given the fact that the 34P93 hybrid maize plant of Cunnyingham is capable of transferring said relative traits, and that these same traits are also affected by the crossing partner, Applicant has failed to adequately distinguish the claimed maize plant from progeny of the 34P93 maize plant of the prior art.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

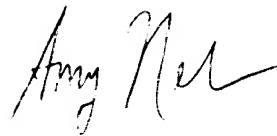
9. Claims 1-8, 20, 21, 33, 34, 41 and 42 are allowed.
10. Claims 9-19 and 22-32 remain rejected and new claims 35-40 are rejected.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



AMY J. NELSON, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

David H. Kruse, Ph.D.
25 February 2003